

Human Exposure Evaluation of SCoR:

The objectives of this new project are three-fold: 1) Determine how SCoR cigarettes are smoked by adult consumers and evaluate their subjective attributes; 2) Determine the exposure of adult smokers of SCoR cigarettes to selected smoke constituents through biomarker sampling; 3) Determine if biomarkers of potential harm change in adult smokers of SCoR cigarettes compared to smokers of light and comparable brand cigarettes. At the conclusion of the project, we anticipate having sufficient data to support a reduced exposure claim for the tested SCoR cigarettes.

The project is comprised of three separate studies. The first, a smoking topography study, is designed to meet the initial project objective. A second study of short term human exposure (ten days) and a final study of long term human exposure (six months) are designed to address the second and third objectives.

Since our experience in this area of research is limited, the current project plan is based upon several assumptions. We are currently conducting a pilot study to examine biomarkers of exposure in adult smokers of electrically heated cigarettes. We expect the completed results from this pilot study in December. Learnings from the pilot study will be incorporated into the final design of the studies for this project.

Timeline Milestones:

Topography Study:

- Final study protocol developed – 4/17/02
- Institutional Review Board (IRB) approval – 7/10/02
- Clinical testing completed – 11/11/02
- Lab analysis completed – 1/6/03
- Final report completed – 4/14/03

Short Term Exposure Study:

- Final study protocol developed – 4/3/02
- Institutional Review Board (IRB) approval – 6/12/02
- Clinical testing completed – 8/30/02
- Lab analysis completed – 12/6/02
- Final report completed – 2/14/03

Long Term Exposure Study:

- Final study protocol developed – 4/4/02
- Institutional Review Board (IRB) approval – 5/29/02
- Clinical testing completed – 5/2/03
- Lab analysis completed – 7/11/03

- Final report completed – 10/3/03

DRAFT FOR REVIEW 10-17-01

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